

公司认证

Company Certification



Certificate of Registration

The Governing Board of
INTERNATIONAL STANDARDS CERTIFICATION LIMITED
hereby grants to:

Nanning TECBOD Biological Technology Co.,Ltd.

Address: Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning , Guangxi,
P.R.China

Has been assessed and found to be in accordance with the requirements of
standard detailed below

ISO 13485:2016

Scope

Production and Sales of Medical Devices
(see attachment for products included)

Authorized by: Blena YP-KO



Certificate No.:ISC3485202033042

Initial Certificate Date:2020-03-18 Certificate Expiration Date:2023-03-17

Note: The time interval between each surveillance audit and the last on-site audit shall not exceed 12 months, the certified clients shall accept regular surveillance audit, the validity of certificates shall be maintained for the positive result of audit.



INTERNATIONAL STANDARDS
CERTIFICATION LIMITED
ROOM 22,13 F,SPEEDY INDUSTRIAL BUILDING,
114 HOW MING STREET,KOWLOON,HONG KONG
Email:info@accredititservice.com
Check the validity of certificate at
www.accredititservice.com



INTERNATIONAL STANDARDS CERTIFICATION LIMITED

Attachment to Certificate

Certificate No.:ISC3485202033042

Organization:

Nanning TECBOD Biological Technology Co.,Ltd.
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao,
Nanning , Guangxi, P.R.China

Scope

Products:

Medical Protective Clothing
Disposable isolation gown
Single-use medical protective overboot
Single-use medical protective hood
Clean air suits
Reusable surgical drapes
Surgical gowns
Single-use surgical gowns
Disposable medical protective bag
Surgical cap
Wash clothes
Medical pads
Medical face-shield
Medical goggle
Latex Examination Gloves

Authorized by: Blena YP-KO

Initial Certificate Date:2020-03-18 Certificate Expiration Date:2023-03-17



INTERNATIONAL STANDARDS
CERTIFICATION LIMITED
ROOM 22,13 F,SPEEDY INDUSTRIAL BUILDING,
114 HOW MING STREET,KOWLOON,HONG KONG
Email:info@accredititservice.com
Check the validity of certificate at
www.accredititservice.com



产品资质

Product qualification

第一类医疗器械生产备案凭证

备案编号: 桂南食药监械生产备20170003号

企业名称	南宁腾科宝迪生物科技有限公司			
住所	南宁市国凯大道19号B2栋6楼601号			
生产地址	南宁市国凯大道19号B2栋6楼601号			
法定代表人	郑清树	企业负责人	雷珍	
生产范围	I 类:14-06与非血管内导管配套用体外器械;14-13手术室感染控制用品;14-14医护人员防护用品;14-15病人护理防护用品;17-04口腔治疗器具			
生产产品列表	产品名称	产品备案号	登载日期	备注
	引流袋(粪便引流装置)	桂南械备20170021号	2018-06-21	
	聚酯衬垫	桂南械备20170023号	2018-06-21	
	手术帽	桂南械备20180050号	2018-08-14	
	洁净服	桂南械备20180066号	2019-09-30	
	洗手衣	桂南械备20180068号	2019-09-30	
	引流管	桂南械备20180078号	2018-12-03	
	医用垫单	桂南械备20190006号	2019-02-22	
	一次性使用口腔器械盒	桂南械备20190044号	2019-11-22	
	一次性医用隔离衣	桂南械备20200008号	2020-02-01	
	医用帽	桂南械备20200011号	2020-02-04	
	医用防护鞋套	桂南械备20200012号	2020-02-11	
	医用隔离鞋套	桂南械备20200013号	2020-02-04	
	医用隔离眼罩	桂南械备20200029号	2020-03-09	
	医用隔离面罩	桂南械备20200030号	2020-03-09	
	医用橡胶检查手套	桂南械备20200031号	2020-03-09	

备案部门(公章): 广西壮族自治区南宁市市场监督管理局
备案日期: 2020年03月10日

GVANGJSIH NANZNINGZ SI SICANGZ GENHDUZ GVANJLILGIZ VANGJCAN 广西南宁市市场监督管理局网站 scjgj.nanning.gov.cn

首页

信息公开

依法行政

办事服务

互动交流

当前位置: 首页 > 依法行政 > 行政审批

一类产品、一类生产备案2020-2-14

发布时间: 2020-02-14 17:25 来源: 南宁市行政审批局

一类产品、一类生产备案2020-2-14

表格名称	操作
一类产品、一类生产备案2020-2-14	下载

打印 分享: +

CE符合性声明

CE Declaration of Conformity

File No: CE-TCF-001

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC

Applicant

Name: Nanning TECBOD Biological Technology Co., Ltd
Address: Room 601 Floor 6, B2 Building, No.19 Guokai Dadao, Nanning , Guangxi, P.R.China



EC Representative

Name: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable medical protective hood
Type: I type: Strip cap (cap fold) II type: Flap cap III type: Lace-up cap

Name: Clean air suits
Type: Conjoined coverall/S、M、L、XL、XXL、XXXL、XXXXL
Split overalls/S、M、L、XL、XXL、XXXL、XXXXL

Name: Disposable surgical gowns
Type: S、M、L、XL、XXL、XXXL

Name: Medical face-shield
Type: Anti-fog type/TKBD2001

Name: Medical goggle
Type: Anti-fog closed type/TKBD1001

Name: Medical latex examination gloves
Type: Powder glaz/6、6.5、7、7.5、8、8.5、9
Powder pitting/6、6.5、7、7.5、8、8.5、9
Powder Free glaze/6、6.5、7、7.5、8、8.5、9
Powder Free pitting/6、6.5、7、7.5、8、8.5、9

Classification: Class I (MDD, Annex IX), Rule 1 (All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2013
EN 166:2002
EN 455:2019
EN 13795-2:2019
EN 13795-1:2019
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2013



欧盟授权代表协议

MDR EU REP Agreement

SUNGO Europe B.V.
SUNGO/ECR/NED/MDR/01 V2.0

Ref. No.: MDR2020M02081

MDR EU REP Agreement

Party A甲方: Nanning TECBOD Biological Technology Co.,Ltd

Add地址: Room 601 Floor 6, B2 Building, No 19 Guokai Dadao, Nanning, Guangxi, P.R.China

Contact联系人: 韦丽巧

Tel电话: +86 0771-3210918

Fax传真: +86 0771-3210918

Email邮箱: 2857994237@qq.com

Party B乙方: SUNGO Europe B.V.

VAT: NL857821659B01

Add地址: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Contact联系人: SUNGO Secretary

Tel电话/Fax传真: +31 (0) 2021 11106

E-mail邮箱: ec.rep@sungogroup.com



Party A hereby appoints Party B as the EU authorized Representative for their Medical Device with CE mark and Party B accepts the appointment to be the EU authorized Representative for Party A in the market of European Union (E.U.). Both parties enter this agreement as follow:

甲方任命乙方为CE医疗产品欧盟授权代表，乙方接受甲方任命，为甲方在欧盟市场的CE医疗产品授权代表。双方签署下列协议：

1. Party A 甲方

1.1 Party A assures to provide the updated technical files of each product category with CE mark to Party B (Product categories relevant information please see the appendix A). If Party A can not provide the required technical file to Party B within 30 days after approval of CE certification or before using CE mark for "self declaration" products, this agreement will be terminated automatically, Party A should take on any aftereffect by itself. The technical files should be the electronic copy (PDF/WORD/JPG/TXT version), the written copy would be submitted if required by the competent authority. Detail of the requirements of the submitted files in appendix B.

甲方确保在认证结束后向乙方提供每一大类带CE标志产品的、最新的技术文档（甲方申请CE认证的产品信息见附录一）。如果甲方在认证结束取得证书之后的30天内，或者“自我声明”产品在使用CE标记之前，仍然没有提供给乙方符合要求的CE技术文档的，本协议自动失效，甲方承担由此引起的所有后果。甲方必须提交电子文档文件，文件可以PDF/WORD/JPG/TXT格式的任何一种提交。书面文件只有在欧盟当局需要审核时才提交乙方。所提交文档内容的要求，详见本协议“附件二”。

1.2 Party A shall keep the Party B informed of any changes or updates of the mentioned information in attachment 1 at all times.

如果附件1中的文件有任何变化或更新，甲方应及时通知乙方。

1.3 If any accident/near accident of products, including any serious adverse event during clinical investigation in premarket stage, happens within boundary of E.U., Party A shall help Party B

SUNGO Europe B.V.
SUNGO/ECR/NED/MDR/01 V2.0

Appendix A

For the following product categories:

申请CE认证的产品名称：

No.	Product name 产品名称	Product classification 产品分类	Product name in Chinese 中文产品名称
1	Disposable medical protective hood	I	医用帽（非灭菌）
2	Clean air suits	I	洁净服（非灭菌）
3	Disposable surgical gowns	I	一次性使用手术衣（非灭菌）
4	Medical face-shield	I	医用隔离面罩（非无菌）
5	Medical goggle	I	医用隔离眼罩（非无菌）
6	Medical latex examination gloves	I	医用橡胶检查手套（非无菌）

FDA注册注明

FDA registration confirmation

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

NANNING TECBOD BIOLOGICAL TECHNOLOGY CO., LTD
Room 601 Floor 6, B2 Building, No 19 Guokai Dadao Nanning,
Guangxi, 530033, CHINA

The facility registration and device listing information:

Owner/Operator Number: 10067979		
Device Listing No.	Product Code	Product Name(s)
D387308	OEA	Protective clothing, Isolation Gown,Clean air suits
D387311	HOY	Medical goggle
D387327	FXP	Shoe cover
D387331	LYU	Glove
D387333	FYE	Disposable surgical gown,surgical gown
D387334	KPY	Face-Shield
D387337	FYF	Medical cap

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Reference Number: 2007US233518
Issue date: Apr.08, 2020

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com



产品信息

product information

产品名称	规格型号	执行标准	国际认证	日产量	功能特点	用途	材质	装箱规格	外箱尺寸	净重/毛重
洁净服	连体式	YY/T0506 EN13795	ISO13485:2016 CE符合性声明 FDA注册	3千件	防泼水、阻菌、防静电、不脱絮，重复使用可达50次	使手术室、洁净车间等净化环境免受室内人员的污染	医用长纤聚酯纤维面料	80件/箱	80*40*52(cm)	40.0kg / 42.0kg

Product name	Models & Specifications	Execution standard	International certification	Daily output	Functional features	Application scope	The material	Packing specification	Carton size	NW/GW
Clean air suits	Conjoined coverall	YY/T0506 EN13795	ISO13485:2016 CE Declaration of Conformity FDA	3,000 pieces	Water-proof, anti-bacteria, anti-static, non-flocculation, repeated use up to 50 times	It is used for wearing on the body of anesthesiologists, itinerant nurses, etc. in the operating room, so that the operating room can not be contaminated by the indoor personnel.	Long fiber polyester fabric	80pairs / carton	80*40*52(cm)	40.0kg / 42.0kg